510(k) Summary

FEB 1 2 2014

510(k) Owner's Name:	Coloplast A/S
Address:	Holtedam 1 3050 Humlebaek, Denmark Establishment Registration: 9610694 Owner/Operator: 8010144
Phone/Fax/Email:	Office: (612) 302-4922 Fax: (612) 287-4138
Name of Contact Person:	Tim Crabtree Regulatory Affairs Manager
Date Prepared:	February 10, 2014
Trade or Proprietary Name:	Restorelle Y Contour Polypropylene Mesh
Common or Usual Name:	Surgical mesh
CFR Number/Product Code:	21 CFR §878.3300/OTO (mesh, surgical, synthetic, urogynecologic, for apical vaginal and uterine prolapse, transabdominally placed)
Predicate Devices:	Restorelle Y Contour (K123914)

Description of Device: Restorelle Y Contour Polypropylene Mesh is constructed of knitted non-absorbable monofilaments of polypropylene, a synthetic polymer. It is designed for the treatment of vaginal vault prolapse. The Y shape design allows the two Y-leg segments to be attached to the anterior and posterior vaginal walls. The base of the Y segment is designed to attach to the sacral ligament.

Indication for Use: Restorelle Y Contour Polypropylene Mesh device is indicated for use as bridging material for sacrocolposuspension and/or sacrocolpopexy (laparotomy, laparoscopic or robotic approach) where surgical treatment for vaginal vault prolapse is warranted.

The Indications for Use statement for the Restorelle Y Contour Polypropylene Mesh is identical to that of its proposed predicate device.

Technological Characteristics Summary: Restorelle Y Contour Polypropylene Mesh has the same technological characteristics as the proposed predicate device include material, dimensions, and design.

Performance Data: The changes proposed in this Special 510(K) were evaluated through sterilization validation and packaging integrity testing.

Conclusions: Restorelle Y Contour Polypropylene Mesh is substantially equivalent to its proposed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 12, 2014

Coloplast A/S
Timothy Crabtree
Regulatory Affairs Manager
1601 West River Road
Minneapolis, MN 55411

Re: K140116
Trade/Device Name: Restorelle® Y Contour Polypropylene Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: OTO
Dated: January 14, 2014
Received: January 16, 2014

Dear Timothy Crabtree,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

1. **Statement of Indications for Use**

Indications for Use

510(k) Number (if known): K140116

Device Name: Restorelle Y Contour Polypropylene Mesh

Restorelle Y Contour Polypropylene Mesh device is indicated for use as bridging material for sacrocolposuspension / sacrocolpopexy (laparotomy, laparoscopic, or robotic approach) where surgical treatment for vaginal vault prolapse is warranted.

Prescription Use ___X___ Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) AND/OR (21 CFR 801 Subpart C)

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Benjamin R. Fisher -S
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Concurrence of CDRH, Office of Device Evaluation (ODE)